IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

In the Matter of the Federal Bureau of Prisons' Execution Protocol Cases LEAD CASE: *Roane et al. v. Barr* THIS DOCUMENT RELATES TO: ALL CASES	Case No. 19-mc-0145 (TSC) **FILED UNDER SEAL**

AMENDED COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

I. Nature of Action

1. Plaintiffs Anthony Battle, Brandon Bernard, Alfred Bourgeois, Chad Fulks, Orlando C. Hall, Norris G. Holder, Jr., Dustin Honken, Corey Johnson, Daniel Lee, Keith Nelson, Jeffrey Paul, Wesley Purkey, James H. Roane, Jr., Julius Robinson, Richard Tipton, and Bruce C. Webster bring this action seeking injunctive and declaratory relief for: (a) violations and threatened violations of their right to due process under the Fifth Amendment of the U.S. Constitution; (b) violations and threatened violations of their right to be free from cruel and unusual punishment under the Eighth Amendment of the U.S. Constitution; (c) violations and threatened violations of their right of access to counsel and the courts under the First, Fifth, and Sixth Amendments of the U.S. Constitution; and (d) violations and threatened violations of the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* ("APA"), the Federal Death Penalty Act, 18 U.S.C. § 3591 *et seq.* ("FDPA"), the Food, Drug, and Cosmetic Act 21, U.S.C. § 301 *et seq.* ("FDCA"), and the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA").

2. Plaintiffs Mr. Battle, Mr. Bernard, Mr. Bourgeois, Mr. Fulks, Mr. Hall, Mr. Holder, Mr. Lee, Mr. Nelson, Mr. Paul, Mr. Purkey, Mr. Robinson, and Mr. Webster were sentenced to death pursuant to the FDPA. Plaintiffs Mr. Honken, Mr. Johnson, Mr. Roane, Mr. Robinson, and Mr. Tipton were sentenced to death pursuant to the Anti-Drug Abuse Act of 1988 ("ADAA"), 21 U.S.C. § 848(e), which was part of the CSA. The sentences of all Plaintiffs are governed by the FDPA. Defendants include the individuals who are charged with carrying out the Plaintiffs' death sentences.

3. On July 25, 2019, the United States Department of Justice ("DOJ") announced that executions of federal prisoners, including Plaintiffs, will be administered by the Federal Bureau of Prisons ("BOP") using a revised addendum to the BOP Execution Protocol (the "2019 Addendum") released the same day. The 2019 Addendum provides that all federal executions will be conducted via a uniform procedure utilizing intravenous injection of five grams of Pentobarbital Sodium ("pentobarbital"), a controlled substance under the CSA.

4. On November 13, 2019, the DOJ publicly filed the Administrative Record, which included a revised BOP Execution Protocol that replaced the prior version. (The new BOP Execution Protocol announced by the DOJ and the 2019 Addendum are sometimes referred to herein collectively as the "2019 Protocol.")

5. Upon information and belief, Defendants intend to carry out the execution of Plaintiffs pursuant to the 2019 Protocol, and, as required under the 2019 Protocol, the executions of the Plaintiffs will be administered at the United States Penitentiary in Terre Haute, Indiana ("USP Terre Haute").

6. The sentence of each Plaintiff has become final (with the exception of Mr. Webster, whose death sentence was vacated by the District Court for the Southern District of Indiana and is the subject of a pending appeal before the Seventh Circuit).

7. As described more fully below, the implementation and use of the 2019 Protocol violates Plaintiffs' rights under the First, Fifth, Sixth, and Eighth Amendments of the U.S. Constitution, and violates the APA, the FDPA, the FDCA, and the CSA.

8. Accordingly, Plaintiffs seek the following relief in this action: (a) a preliminary and permanent injunction preventing the Defendants from executing them pursuant to the 2019 Protocol; (b) an order declaring that the implementation or use of the 2019 Protocol violates Plaintiffs' rights under the First, Fifth, Sixth, and Eighth Amendments of the U.S. Constitution; (c) an order declaring that the adoption and use of the 2019 Protocol violates the APA, the FDPA, the FDCA, and the CSA; and (d) any such other equitable relief as this Court deems just and proper.

9. The claims in this Amended Complaint are cognizable under the constitutional and statutory grounds identified herein and described in more detail below. This action is not, and should not be treated as, a successor habeas corpus petition. Plaintiffs are not challenging through this action the validity of their convictions or death sentences. Rather, Plaintiffs assert that the 2019 Protocol, by which—upon information and belief—their executions are to be implemented, violates the Constitution, the APA, the FDPA, the FDCA, the CSA, and other applicable laws.

II. Parties

10. Plaintiff Anthony Battle is a United States citizen whose death sentence was imposed in the State of Georgia. Mr. Battle is incarcerated at the United States Medical Center for Federal Prisoners in Springfield, Missouri under the control and supervision of the BOP, an agency within the DOJ.

11. Plaintiff Brandon Bernard is a United States citizen whose death sentence was imposed in the State of Texas. Mr. Bernard is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

12. Plaintiff Alfred Bourgeois is a United States citizen whose death sentence was imposed in the State of Texas. Mr. Bourgeois is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

13. Plaintiff Chad Fulks is a United States citizen whose death sentence was imposed in the State of South Carolina. Mr. Fulks is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

14. Plaintiff Orlando C. Hall is a United States citizen whose death sentence was imposed in the State of Texas. Mr. Hall is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

15. Plaintiff Norris G. Holder, Jr. is a United States citizen whose death sentence was imposed in the State of Missouri. Mr. Holder is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

16. Plaintiff Dustin Honken is a United States citizen whose death sentence was imposed in the State of Iowa. Mr. Honken is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

17. Plaintiff Corey Johnson is a United States citizen whose death sentence was imposed in the Commonwealth of Virginia. Mr. Johnson is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

18. Plaintiff Daniel Lee is a United States citizen whose death sentence was imposed in the State of Arkansas. Mr. Lee is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

19. Plaintiff Keith Nelson is a United States citizen whose death sentence was imposed in the State of Missouri. Mr. Nelson is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

20. Plaintiff Jeffrey Paul is a United States citizen whose death sentence was imposed in the State of Arkansas. Mr. Paul is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

21. Plaintiff Wesley Purkey is a United States citizen whose death sentence was imposed in the State of Missouri. Mr. Purkey is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

22. Plaintiff James H. Roane, Jr. is a United States citizen whose death sentence was imposed in the Commonwealth of Virginia. Mr. Roane is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

23. Plaintiff Julius Robinson is a United States citizen whose death sentence was imposed in the State of Texas. Mr. Robinson is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

24. Plaintiff Richard Tipton is a United States citizen whose death sentence was imposed in the Commonwealth of Virginia. Mr. Tipton is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

25. Plaintiff Bruce C. Webster is a United States citizen whose death sentence was imposed in the State of Texas. Mr. Webster is incarcerated at USP Terre Haute under the control and supervision of the BOP, an agency within the DOJ.

26. Defendant William P. Barr is the Attorney General of the United States. Plaintiffs were remanded into the Attorney General's custody upon their conviction and the imposition of their death sentences. Under the 2019 Protocol, Attorney General Barr is the executive responsible for carrying out sentences of death against federal prisoners. Attorney General Barr is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

27. Defendant Timothy Shea is the Acting Administrator of the U.S. Drug Enforcement Administration ("DEA"). In that role, Mr. Shea is responsible for overseeing all controlled substances, including pentobarbital (a Schedule II drug under the CSA). Mr. Shea is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

28. Defendant Stephen M. Hahn, M.D., is the Commissioner of Food and Drugs at the Food and Drug Administration ("FDA"). As Commissioner, Defendant Hahn is responsible for overseeing drugs that are regulated by the FDA and that otherwise fall under the FDCA, 21 U.S.C. § 301 *et seq.*, including compounded and non-compounded pentobarbital. Dr. Hahn is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

29. Defendant Michael Carvajal is the Director of the United States Bureau of Prisons. As such, he is charged with prescribing and directing the promulgation of rules and regulations for the BOP, including the rules and regulations for the conduct of prison operations and, under the

2019 Protocol, execution procedures. Mr. Carvajal is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

30. Defendant Jeffrey E. Krueger is the Regional Director of the North Central Region of the BOP. Mr. Krueger is responsible for operations at USP Terre Haute, and plays a role in the promulgation of rules and regulations for USP Terre Haute, including rules and regulations for the conduct of prison operations and executions. Mr. Krueger is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

31. Defendant Donald W. Washington is the Director of the U.S. Marshals Service ("USMS") and is responsible for all agency operations. Under Section 3596 of the FDPA, a U.S. Marshal "shall supervise implementation" of Plaintiffs' death sentences "in the manner prescribed by the law of the State in which the sentence is imposed." Mr. Washington is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

32. Defendant Nicole C. English is the Acting Assistant Director, Health Services Division, of the BOP. Ms. English is responsible for overseeing the provision of medical care to prisoners at all BOP facilities, including USP Terre Haute, and for promulgating and implementing BOP policies with respect to medical care provided by the BOP. Ms. English is sued here in her official capacity for the purpose of obtaining declaratory and injunctive relief.

33. Defendant T.J. Watson is the Complex Warden of USP Terre Haute. Mr. Watson is responsible for the management, oversight and operations at USP Terre Haute, including the oversight and implementation of executions. Mr. Watson is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

34. Defendant William Wilson, M.D., is the Clinical Director at USP Terre Haute. In that position, he is responsible for overseeing the provision of medical care to prisoners at that facility.

Dr. Wilson is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

35. The Defendants identified in Paragraphs 29-30, 32-34 above will be referred to below as the "BOP Defendants."

36. Defendants John Does I - X (the "John Doe Defendants") are employed by, or have contracted with, the BOP to provide consultations for, prepare for, and/or carry out the Plaintiffs' executions. The Plaintiffs do not know, and the BOP Defendants have refused to reveal, the identities or positions of the John Doe Defendants. To the extent the John Doe Defendants are federal government employees, they are sued here in their official capacities for the purpose of obtaining declaratory and injunctive relief.

37. Upon information and belief, unless preliminarily and permanently enjoined, the BOP Defendants will act in their respective official capacities and under the authority of federal law in executing the Plaintiffs, in violation of the Plaintiffs' constitutional and/or statutory rights. The foregoing allegation applies to the John Doe Defendants to the extent they are federal government employees.

III. Jurisdiction and Venue

38. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331 and 28 U.S.C. § 1343 because this action arises and seeks relief under the laws and Constitution of the United States, specifically, the First, Fifth, Sixth, and Eighth Amendments of the U.S. Constitution, the APA, 5 U.S.C. §§ 702-706, 28 U.S.C. § 2201 (declaratory relief), and 28 U.S.C. § 2202 (injunctive relief).

39. Venue is proper under 28 U.S.C. § 1391(b)(2) because the BOP headquarters is in this District and a substantial part of the events giving rise to the claims made herein by Plaintiffs,

including the formulation and authorization of the 2019 Protocol, took place and continue to take place in this District.

IV. Factual Background

A. The History of the Federal Lethal Injection Protocol

40. Beginning in 1937, Congress required federal executions to be conducted in the manner prescribed by the state of conviction. *See* 50 Stat. 304 (formerly 18 U.S.C. § 542 (1937)), recodified as 62 Stat. 837 (formerly 18 U.S.C. § 3566) (the "1937 Act"). Upon information and belief, the USMS supervised the implementation of federal executions pursuant to the 1937 Act.

41. The death penalty was briefly held unconstitutional. *See Furman v. Georgia*, 408 U.S. 238 (1972). The Supreme Court's decision in *Gregg v. Georgia*, 428 U.S. 153 (1976), reaffirmed the constitutionality of the death penalty.

42. In 1984, Congress repealed the 1937 Act, leaving the federal government without a mechanism for carrying out executions. In 1988, Congress passed the Anti-Drug Abuse Act, which reinstated the death penalty for certain federal crimes but did not specify a procedure for implementation.

43. On November 30, 1992, the DOJ published a proposed rule seeking to "establish[] procedures" for carrying out federal death-penalty sentences. Implementation of Death Sentences in Federal Cases, 57 Fed. Reg. 56,536 (Nov. 30, 1992) (to be codified at 28 C.F.R. pt. 26). The DOJ received and considered comments from (among others) medical associations, physicians, criminal defense attorneys, and advocates for prisoners' rights.

44. On February 18, 1993, the DOJ issued a set of regulations, referred to as the "Final Rule," that purported to establish a protocol for carrying out the executions of prisoners "sentenced to death for commission of an offense described in any federal statute." 28 C.F.R. § 26.1. The Final Rule provided that executions would take place at a federal prison by

"intravenous injection of a lethal substance." *Id.* § 26.3(a)(4). The Final Rule provided little detail about the manner of execution and did not identify the drug or drugs to be used in executions. In addition, the Final Rule did not provide for any role for the USMS in connection with the implementation of death sentences.

45. In 1994, Congress enacted the FDPA, establishing that federal death sentences shall be implemented as follows:

> When the [death] sentence is to be implemented, the Attorney General shall release the person sentenced to death to the custody of a United States marshal, who shall supervise implementation of the sentence in the manner prescribed by the law of the State in which the sentence is imposed.

18 U.S.C. § 3596(a). The FDPA superseded the Final Rule and once again assigned to the USMS sole responsibility and authority to supervise the implementation of federal death sentences.

46. The FDPA provides only one exception to this "law of the State" requirement: "If the law of the State does not provide for implementation of a sentence of death, the court shall designate another State, the law of which does provide for the implementation of a sentence of death, and the sentence shall be implemented in the latter State in the manner prescribed by such law." 18 U.S.C. § 3596(a). The FDPA therefore does not provide or contemplate the establishment of a separate, uniform federal execution protocol or procedure.

47. The FDPA also does not grant any authority to the BOP to create a uniform federal execution protocol, set execution dates, times, or places, or administer executions.

48. Following enactment of the FDPA in 1994, there were several legislative attempts, all supported by the DOJ and the BOP, to amend the FDPA to eliminate the requirement that death sentences be implemented "in the manner prescribed by the law of the State in which the sentence is imposed," and, instead, grant authority to the BOP to devise and implement procedures and protocols for the executions of prisoners sentenced under the FDPA. All of those efforts failed.

None of the proposed amendments to the FDPA were enacted by Congress, and the FDPA continues to require the federal government to carry out executions in the manner prescribed by the law of the state in which the prisoner's sentence was imposed and continues to assign sole authority and responsibility to the USMS to supervise the implementation of federal death sentences.

49. In 2004, the DOJ, without notice or comment, adopted a new BOP Execution Protocol for carrying out federal death penalty sentences (the "2004 Protocol"). The 2004 Protocol included additional detail about how executions would be administered, but was silent about the drug or drugs to be used in executions.

50. In December 2005, several of the Plaintiffs initiated this action by challenging the 2004 Protocol as violating the APA, the CSA, and their rights pursuant to the Fifth and Eighth Amendments of the U.S. Constitution. This Court issued preliminary injunctions preventing the executions of those Plaintiffs during the pendency of the litigation.

51. While this litigation was pending, the BOP updated the 2004 Protocol by issuing addenda in 2007 and 2008 (the "2008 Addendum"). The 2008 Addendum specified that executions would be carried out using three drugs: sodium pentothal, pancuronium bromide, and potassium chloride. (The 2004 Protocol and 2008 Addendum will collectively be referred to as the "2008 Protocol.")

52. In May 2011, the BOP announced that it did not have the drugs necessary to implement the 2008 Protocol and was considering revisions to the execution protocol. After the announcement by the BOP that it was unable to implement the 2008 Protocol, the ongoing litigations were stayed. For the next eight years, the DOJ submitted quarterly status reports indicating that protocol revisions were ongoing.

53. On July 25, 2019, the DOJ issued a press release announcing the scheduling of five executions: three within a single week in December 2019, and another two during a single week in January 2020, all to be carried out at USP Terre Haute.

54. On the same day, the DOJ announced that, at the direction of Attorney General Barr, the BOP had adopted the 2019 Addendum. The 2019 Addendum replaced the previous three-drug procedure with a procedure using a five-gram dose of pentobarbital.

55. On November 13, 2019, the BOP publicly filed the Administrative Record, including a revised execution protocol (the 2019 Protocol) which replaced the 2008 Protocol. (The Administrative Record was supplemented twice thereafter.) The 2019 Protocol included the 2019 Addendum and also removed key provisions that had been included in the 2008 Protocol, including a detailed plan for responding to unexpected occurrences during executions.

56. The 2019 Protocol, including the 2019 Addendum, constitute DOJ/BOP "statement[s] of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency." 5 U.S.C. § 551(4). They are therefore "rule[s]," as defined by the APA. *Id.*

57. The 2019 Protocol was adopted by the BOP and the DOJ without any advance notice to the Plaintiffs or the public. Between the BOP's May 2011 announcement that it was unable to implement the 2008 Protocol and the July 25, 2019 announcement of the 2019 Addendum and five execution dates, neither the DOJ nor the BOP provided any information to the public or to Plaintiffs about the 2019 Protocol, the 2019 Addendum, or any of the other processes or details of any revisions to the execution protocol that were planned or under discussion or consideration.

58. Neither the DOJ nor the BOP followed the applicable rule-making process under the APA, which requires an agency to publish proposed rules in advance of adoption and allows the

public an opportunity to comment on such policy changes before they are put into place. *See, e.g.*, 5 U.S.C. § 553.

B. The 2019 Protocol

1. The 2019 Protocol Violates Applicable Law.

59. The FDPA expressly provides that a "United States marshal . . . shall supervise implementation of the sentence in the manner prescribed by the law of the State in which the sentence is imposed." 18 U.S.C. § 3596(a).

60. The 2019 Protocol flouts that Congressional directive and violates the FDPA by purporting to establish and implement for all federal executions a separate and uniform federal execution protocol that, upon information and belief, does not follow and is materially different from the manner prescribed by the law of the States in which Plaintiffs' sentences were imposed. *See* Appendix A attached hereto. Upon information and belief, Defendants will utilize the procedures identified in the 2019 Protocol, instead of the procedures deemed binding by the law of each State where Plaintiffs were sentenced. In the alternative, to the extent the Court finds that the 2019 Protocol grants Defendants the discretion to change or depart from the procedures laid out in the 2019 Protocol in order to implement executions in the manner prescribed by the laws of the States, Defendants have failed to provide notice of which States' procedures they will follow and what changes they will make to comply with the binding law of those States.

61. The 2019 Protocol also violates the FDPA by purporting to delegate to the BOP the responsibility to supervise implementation of death sentences, a responsibility expressly reserved and assigned by Congress to the USMS. Moreover, despite the FDPA's specific assignment of responsibility to the USMS to supervise the implementation of federal death sentences, the USMS had no meaningful role or participation in the creation or preparation of the 2019 Protocol. *See* Sheehan Dep. at 24:1-20, 30:20-31:7.

62. The CSA makes it unlawful to "dispense" any "controlled substance" except pursuant to a valid prescription "issued for a legitimate medical purpose" by a practitioner who is registered pursuant to the statute and is "acting in the usual course of his professional practice." 21 U.S.C. §§ 822, 829, 841(a)(1); 21 C.F.R. § 1306.04(a). In addition, regulations promulgated by the DEA provide that every person who "dispenses" a "controlled substance" is required to obtain a registration, and that the DEA Administrator "shall deny" an application for registration unless the issuance of a registration is "required" under the CSA. 21 C.F.R. § 1301.35.

63. Defendants have confirmed that they do not intend to obtain a prescription for the pentobarbital they intend to use to execute Plaintiffs. *See* Miller Dep. at 29:18-21.

64. The 2019 Protocol violates the CSA because it requires the dispensing and administration of pentobarbital (a Schedule II controlled substance) without a valid prescription for no legitimate medical purpose, by persons who are not acting in the course of professional practice and/or who lack a valid registration, and by not requiring the persons who will dispense the pentobarbital to apply for a registration.

65. The FDCA, which applies to drugs used in lethal injection executions, conditions the dispensing of FDA-approved drugs such as pentobarbital upon either (a) "a written prescription of a practitioner licensed by law to administer such drug," or (b) "an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist." 21 U.S.C. § 353(b)(1)(B).

66. A prescription must be a "bona fide order" reflecting a genuine practitioner-patient relationship. *United States v. Nazir*, 211 F. Supp. 2d 1372, 1375 (S.D. Fla. 2002). It directs "the preparation and administration of a medicine, remedy, or drug for a real patient who actually needs it after some sort of examination or consultation by a licensed doctor—and does

not include pieces of paper by which physicians are directing the issuance of a medicine, remedy, or drug to patients who do not need it, persons they have never met, or individuals who do not exist." *Id.*

67. The 2019 Protocol violates the FDCA because it requires the dispensing and administration of pentobarbital and/or compounded pentobarbital without a valid medical prescription. Medical prescriptions are available for pentobarbital and/or compounded pentobarbital as evidenced by the fact that two of the five states whose methods Defendants relied on in crafting the 2019 Protocol utilize such prescriptions.

68. The FDCA also prohibits compounding of a drug that is "essentially a copy of one or more approved drugs." 21 U.S.C. § 353b(a)(5). Upon information and belief, the compounded pentobarbital Defendants intend to use to execute Plaintiffs is "essentially a copy" of, is "identical or nearly identical to," and contains a "bulk drug substance" contained in, FDA-approved pentobarbital, including Nembutal and generic products. 21 U.S.C. § 353b(d)(2)(A)-(B).

69. The 2019 Protocol violates the FDCA because FDA-approved pentobarbital, including Nembutal and generic products, are marketed and commercially available drug products under the FDCA.

70. Under the APA, any agency action that is "not in accordance with [the] law," "in excess of statutory jurisdiction, authority, or limitations," "contrary to constitutional right, power, privilege, or immunity," or taken "without observance of procedure required by law" must be set aside. 5 U.S.C. § 706(2)(A)-(D).

71. The 2019 Protocol violates the FDPA, the CSA, and the FDCA, is thus "not in accordance with [the] law," and under the APA must be set aside. In addition, the 2019 Protocol violates the APA because the DOJ and the BOP failed to provide advance notice or opportunity

for the public to comment upon the 2019 Protocol prior to its promulgation, and its adoption was not the product of reasoned decision-making.

2. Issues with Pentobarbital.

72. The 2019 Protocol provides that "[t]he lethal substances to be utilized in federal lethal injections shall be Pentobarbital Sodium." 2019 Addendum, ¶ C. The 2019 Protocol further provides that executions will be administered using two syringes each containing "2.5 grams of Pentobarbital Sodium in 50 mL of diluent," and a third syringe containing "60 mL of saline flush." *Id.* ¶ H.

73. Pentobarbital is a barbiturate that affects the activity of the brain and nervous system. It is clinically indicated for use as a pre-anesthetic, a sedative, and for treatment of brain-swelling, seizures, and insomnia.

74. Barbiturates such as pentobarbital "do not guarantee lack of consciousness." Decl. of Gail Van Norman, M.D. ("Van Norman Decl."), at 7 (Nov. 11, 2019), ECF No. 24. Pentobarbital produces only unresponsiveness, not unconsciousness or lack of awareness, so prisoners given a five-gram dose of pentobarbital will remain sensate and feel the effects of the execution. "[E]ven when the patients appear to be unconscious by all clinical measures and are unresponsive, . . . consciousness will permit extreme pain and suffering during the execution process." *Id.*

75. Pentobarbital has a high alkaline pH of approximately 9.5, significantly higher than normal blood pH. Defendants' supplies of pentobarbital, to the extent they have been analyzed and disclosed, show even higher pH readings, specifically, 9.91, 10.0, 10.03, 10.3, and 10.12. Decl. of Mark A. Edgar, M.D. ("Edgar Decl."), at 19 (Oct. 24, 2019), ECF No. 26-12.

76. As a result of pentobarbital's high pH level, injection of a high dose of pentobarbital (including five grams as required by the 2019 Protocol) will cause "flash" or non-cardiogenic pulmonary edema "virtually instantaneous[ly]." Van Norman Decl. at 33. Flash pulmonary

edema results from the "direct toxic/caustic damage to the lung capillaries as extremely high concentrations of barbiturates (which are highly alkaline and caustic) make physical contact with the lung and capillary surfaces, causing immediate leakage of fluid through the damaged capillaries into the lungs." *Id.* at 32; *see also* Edgar Decl. at 19-20. Flash or non-cardiogenic pulmonary edema is distinguished from cardiogenic pulmonary edema, which occurs much more gradually when fluid backs up in the lungs as a result of heart failure. *See* Edgar Decl. at 3.

77. Flash pulmonary edema will produce "foam or froth in the small/lower or large/upper airways (bronchi and trachea) resulting from the mixture of air, edema fluid, and pulmonary surfactant (a detergent-like secretion normally present in the airspaces)." Edgar Decl. at 4. As a result, flash pulmonary edema causes "obstruction or partial obstruction of the upper airway due to effects of barbiturates on respiratory centers in the brain, or due to laryngospasm (a spasmodic, involuntary closure of the larynx) while respiratory efforts continue against the obstruction or partial obstruction, 'sucking' fluids from the capillaries into the lung air spaces"—a mechanism known as "negative pressure pulmonary edema." Van Norman Decl. at 32. Pulmonary edema may also result from "acute left heart failure due to direct toxic effects of barbiturates on the heart, leading to 'backing up' of blood into the lungs." *Id.*

78. The experience of acute pulmonary edema prior to the loss of consciousness "produces sensations of drowning and asphyxia," and therefore, "the experience of this condition in an inmate who was still sensate would result in extreme pain, terror and panic," Edgar Decl. at 21, feelings made "more frightening by being positioned lying flat in restraints," "which aggravates the noxious sensations of pulmonary edema." *Id.* at 22. Pulmonary edema causes an "excruciating" experience comparable to death by drowning.

> Not being able to breathe during drowning or asphyxiation is one of the most powerful, excruciating feelings known to man. It is nearly impossible for most

> untrained human beings to hold their breath voluntarily for more than 1 minute. In less than 60 seconds, sensations of asphyxia and compulsion to breathe appear and rapidly overwhelm the brain. Panic and terror, and the attempt to fight take over. Even human beings who are underwater will reach such a level of agony that they will be compelled to take a "breath" within about 1 minute. This is the sensation that is deliberately elicited in "the enhanced interrogation technique" called waterboarding, which is defined by the European Court of Human Rights as a form of torture.

Van Norman Decl. at 34 (emphasis omitted).

79. "Flash" or "acute" pulmonary edema occurs in the "vast majority, if not all" of pentobarbital executions. Van Norman Decl. at 31.

80. Flash pulmonary edema occurs "virtually immediately during and after high-dose barbiturate injection," and well within the time frame for pentobarbital to carry out its peak effects on the brain. Van Norman Decl. at 36. It is therefore "extremely likely" that prisoners executed with pentobarbital will experience sensations of drowning and suffocation when they die. *Id.* It is likewise "extremely likely" that prisoners who are injected with five grams of pentobarbital under the 2019 Protocol will remain "capable of feeling pain, terror, and suffocation." *Id.* at 7. And it is a "virtual medical certainty that most, if not all, prisoners will experience excruciating suffering, including sensations of drowning and suffocation, as a result of [the] effect of IV injection of 5 grams of pentobarbital." *Id.*

81. A review of over two dozen autopsy reports confirms that it is a "virtual medical certainty" that most, if not all, prisoners executed with a single dose of pentobarbital, as is contemplated by the 2019 Protocol, experienced "immediate, flash pulmonary edema," which is not a normal autopsy finding. Van Norman Decl. at 36. Prisoners' autopsy reports also confirmed the presence of moderate to severe pulmonary edema, "many with fluid filling their major airways." *Id.* at 35. The presence of froth, foam or fluid in the airways indicated the onset of flash, non-cardiogenic pulmonary edema (not cardiogenic pulmonary edema) caused by

"immediate toxic damage to the pulmonary capillaries by the" pentobarbital, *id.* at 35-36, and further indicated that the prisoners continued to breathe after the onset of the edema—as demonstrated by the mixing of edema-fluid and air. *Id.* at 36; *see also* Edgar Decl. at 18, 20.

82. Witness reports of executions also confirm that prisoners who were executed with a single dose of pentobarbital were sensate and continued to breathe after the onset of the edema, and, before losing consciousness, experienced acute symptoms of pulmonary edema, including burning sensations, labored breathing, gasping, and other signs of severe pain and respiratory distress. *See* Edgar Decl. at 19-21.

83. Based on the foregoing, there is "an extremely high risk" that the 2019 Protocol will "caus[e] prisoners severe pain, and is virtually certain to cause prisoners excruciating suffering through their awareness of the sensations of suffocation and drowning caused by pulmonary edema." Van Norman Decl. at 6-8.

84. The 2019 Protocol lacks sufficient detail and important requirements and safeguards to ensure that the pentobarbital Defendants obtain for use in executions will meet minimum standards of purity and potency and function as intended. The problems attendant to the use of pentobarbital in executions are made significantly worse if the drug is contaminated, impure, sub-potent, or otherwise does not meet minimum standards of purity and potency, including pentobarbital that has expired, is past its "beyond use date," or has failed established quality control measures.

85. Under those conditions, the pentobarbital "would not have the pharmacological effect as expected, potentially leading to the prisoner's prolonged suffering as a result." Decl. of Michaela Almgren, Pharm.D., M.S. ("Almgren Decl.") at 8 (Oct. 31, 2019), ECF No. 26-15. Accordingly, the lack of requirements and safeguards in the 2019 Protocol materially and

foreseeably increase the likelihood that prisoners will suffer severe pain and serious harm during executions.

a. The 2019 Protocol contains no provisions, requirements, criteria, or safeguards regarding the methods for obtaining, storing, mixing, and appropriately labeling the pentobarbital; the chain of custody for the pentobarbital; or the minimum qualifications and expertise required for the person who will be determining the concentration, dosage, and rate of infusion to give. As to those crucial points, it instead provides unfettered discretion without even the criteria to guide the exercise of that discretion.

b. The 2019 Protocol does not require or allow for the consideration of the prisoner's unique physical health and medical conditions and history as part of the determination of the appropriate dosage to be used. Rather, the 2019 Protocol fixes the same dosage to be used in every execution. *See* 2019 Addendum, ¶ H.

c. The 2019 Protocol contains no provisions, requirements, criteria, or safeguards regarding the form and provenance of the pentobarbital to be used (manufactured, FDA-approved, compounded, imported, etc.).

d. The 2019 Protocol contains no provisions, requirements, criteria, or safeguards regarding testing of the pentobarbital to be used in executions to ensure, at a minimum, its identity, purity, and potency. Nor does the 2019 Protocol contain any requirements or safeguards to ensure that pentobarbital that fails any quality assurance testing will not be used in any execution.

e. The 2019 Protocol also lacks any requirement that the results of any testing the BOP elects to undertake are communicated promptly and prior to the execution to condemned prisoners facing execution and their counsel. These are not abstract concerns. The pentobarbital

prepared for use in the executions scheduled for December 2019 failed quality assurance testing on or around December 3, 2019, but Defendants informed neither Plaintiffs nor this (or any other) Court of that failure, despite ongoing litigation over whether those executions would be enjoined. Plaintiffs only learned of the failed test on January 29, 2020 during the OAG 30(b)(6) deposition of Mr. Weinsheimer. Defendants have further revealed that none of their lethal injection drugs had passed quality assurance testing at the time of the first scheduled execution, but intended to proceed regardless, had its injunction been lifted. May 2020 Winter Dep. at 56:3-60:2.

86. For the foregoing reasons, the 2019 Protocol "will subject executed prisoners to severe pain and suffering, when they remain conscious and aware prior to their deaths." Van Norman Decl. at 6-7.

3. Issues with Compounded Pentobarbital.

87. The BOP has advised Plaintiffs that it has obtained pentobarbital active pharmaceutical ingredient ("API") from a domestic manufacturer, has identified a compounding pharmacy to store the API and compound an injectable form of the drug, and currently intends to use compounded pentobarbital to administer Plaintiffs' executions. *See* AR 872.

88. The 2019 Protocol lacks sufficient detail and important requirements and safeguards to ensure that compounded pentobarbital used in executions meets minimum standards of purity and potency. Use of contaminated, impure, or sub-potent compounded pentobarbital materially and foreseeably increases the likelihood that prisoners will suffer severe pain and serious harm during executions. *See* Almgren Decl. at 7-8.

89. Compounded drugs are not FDA-approved and are subject to less rigorous regulation and oversight relating to the identity, purity, and potency of the drug. For these reasons, there is

a substantial risk that compounded drugs will be contaminated, handled improperly or suffer from quality issues, the most common and concerning of which is lack of potency.

90. The BOP has stated that the compounding facility that will produce pentobarbital for federal executions is a registered outsourcing facility pursuant to section 503B of the FDCA, 21 U.S.C. § 353b (*see* Nov. 2019 Winter Dep. at 291:10, 307:2-4; Decl. of Raul Campos at 1-2 (Nov. 12, 2019), ECF No. 36-1)), but the DEA has advised that the facility is not a compounding pharmacy, but rather a dosage manufacturer. *See* Miller Dep. at 78:6-17.

91. This confusion is made worse by the fact that the 2019 Protocol contains no provisions, requirements, criteria, or safeguards to ensure verification that the API supplier and compounding pharmacy are qualified, experienced, properly licensed, and have a satisfactory regulatory track record.

92. The BOP has advised Plaintiffs that it found the API supplier and compounding pharmacy it allegedly has secured by "cold-calling" pharmacies and manufacturers, Nov. 2019 Winter Dep. at 301:2-17, 310:5-10, and the Office of the Attorney General advised that the chosen compounding facility had no previous experience compounding pentobarbital, Weinsheimer Dep. at 217:2-5, raising quality concerns given the technical complexity of compounding the drug properly. *See* Almgren Decl. at 2-4. But Defendants have provided no additional information about the process and criteria for vetting and selecting the supplier of the API or the compounding pharmacy, including sufficient information to verify they are qualified, experienced, properly licensed, adhere to appropriate standards and practices, and have a satisfactory regulatory record.

93. Compounding of pentobarbital is a complex and highly specialized process that requires specialized equipment, numerous pharmaceutical-grade ingredients, chemical

adjustments during the process, and of course the appropriate experience and credentials in aseptic compounding technique. *See* Almgren Decl. at 2-3.

94. Even minor deviations from the complex procedures for compounding pentobarbital can result in a sub-potent drug. *See* Almgren Decl. at 4. The use of a sub-potent drug increases the risk of severe pain and harm because it "would not have the pharmacological effect as expected, potentially leading to the prisoner's prolonged suffering as a result." *Id*. at 7-8.

95. The 2019 Protocol lacks information explaining how the pentobarbital Defendants intend to use for executions has been compounded or will be compounded. In particular, the 2019 Protocol lacks detail and contains no requirements to ensure that the pentobarbital is properly compounded in accordance with applicable standards and best practices. It omits any discussion of: the quality of the API; an appropriate formulation recipe; the procedures by which the drug has been or will be compounded; the ingredients and their concentrations; the equipment used and how that equipment is maintained and calibrated; or the contents of "compounding logs" that include the criteria used to determine the beyond use date, a master work sheet containing storage requirements, and documentation of performance of quality control procedures. *See* Almgren Decl. at 4. Without that information, it is impossible to verify that the pentobarbital to be used in executions has been properly compounded and is "safe to be used without causing unnecessary suffering to the prisoner." *Id.*; *see also* Van Norman Decl. at 8 & 41.

96. Proper compounding also involves standards for proper storage of drugs including temperature, humidity, and sterile conditions. Storage conditions must be continually monitored and documented. Improper storage, such as excessive temperature, excessive humidity, or unsterile conditions, will cause drugs—the API powder or the compounded form—to be

degraded, contaminated, or damaged. This increases the "risk that the drugs could lose potency and thus the drugs would not have the pharmacological effect as expected, potentially leading to the prisoner's prolonged suffering as a result." Almgren Decl. at 7-8. The 2019 Protocol lacks detail and contains no requirements to ensure that these critical storage requirements are satisfied and that sub-potent and/or expired drugs are not used in executions.

97. Compounded drugs, including pentobarbital, are subject to standards for shelf-life or "use by" dates, and the allowable length of time between compounding and administration. *See* Almgren Decl. at 5. If administered after the "beyond use date," the drug may be unstable or unsterile and thus lose potency. The 2019 Protocol lacks detail and contains no requirements to ensure that drugs past their "beyond use date" are not used in executions.

98. If Defendants carry out executions using compounded pentobarbital, there is a substantial and foreseeable risk that the drugs will be handled improperly, contaminated, and sub-potent, and thus a substantial and foreseeable risk that Plaintiffs will suffer severe pain and substantial harm during executions.

4. Issues with Intravenous ("IV") Administration of Pentobarbital.

99. The 2019 Protocol provides that "[l]ethal substances shall be administered intravenously." 2019 Addendum, ¶ H. Setting an intravenous line is a delicate, complicated, and invasive procedure that requires appropriate and extensive skill, experience, and training. Ensuring that intravenous access is properly established, functioning, maintained, and monitored is essential to ensure that lethal injection will effectively bring about death in a humane and constitutional manner.

100. Proper establishment and maintenance of intravenous access throughout the execution is necessary to ensure that drugs are properly and humanely administered to the prisoner.

101. Improper IV insertion may lead to infiltration (in which the drug is injected or bursts into the surrounding tissue instead of the prisoner's vein) or extravasation (leakage of the drug into the surrounding tissue). *See* Van Norman Decl. at 36-37. Extravasation and infiltration often cause "significant, excruciating pain for prisoners," including "instant, excruciating pain that patients liken to being set on fire." *Id.* at 8 & 36. Injection of pentobarbital into an artery instead of a vein may result in "instant arterial spasm, pain, excruciating local tissue destruction, and also immediate ischemia (i.e., lack of oxygen, tissue damage and necrosis) in the area of the body supplied by the artery." *Id.* at 36. Infiltration, extravasation, and arterial injection "can result in slow suffocation if only partial injection is achieved, and a lingering and extremely painful death, and/or failure of the execution altogether." *Id.* at 41.

102. The 2019 Protocol lacks sufficient detail and important requirements and safeguards to ensure that intravenous access is properly established and maintained throughout the execution.

a. The 2019 Protocol contains no criteria or requirements regarding the manner in which the IV catheters shall be inserted into the prisoner (for example, whether to establish central line access or perform a cut-down); whether there is an order of preferred access sites; whether there is a time limit for establishing IV access; whether there is a limit on the number of times the team can attempt IV access; and how disagreements among execution team members are to be resolved. *See* Nov. 2019 Winter Dep. at 225:13-227:12.

b. The 2019 Protocol contains no requirements regarding the minimum training, experience, or qualifications required for the person setting the IV. *See* Nov. 2019 Winter Dep. at 162:20-163:4.

c. The 2019 Protocol contains no requirements regarding the minimum training, experience, or qualifications required for the person who is given the responsibility and

discretion to decide when efforts at inserting the IV catheters should be abandoned in favor of some other constitutionally acceptable procedure, and the manner in which the condition of the prisoner will be monitored to confirm that the IV lines are not inflicting severe and unnecessary pain.

d. The 2019 Protocol contains no criteria or requirements regarding the manner in which the prisoner will be monitored to ensure that he or she is anesthetized and insensate during the entire execution process, or the qualifications and expertise required for the person who will be responsible for such monitoring.

e. The 2019 Protocol contains no criteria or requirements regarding the manner in which the IV tubing, three-way valve, saline solution, or other apparatus shall be modified or repaired in the event it malfunctions during the execution process, the minimum qualifications and expertise required of the person who shall have the discretion to decide to attempt such action, and the criteria that shall be used in exercising this discretion.

f. The 2019 Protocol allows the training and experience of the execution team member placing the IVs to change from one execution to the next, and contains no requirements to ensure that the team member responsible for the critical task of determining the method of venous access has sufficient and appropriate training, experience, and qualifications to undertake the task or make that determination. *See* Nov. 2019 Winter Dep. at 162:20-163:4.

g. The 2019 Protocol does not require that the prisoner's unique physical, health, and medical conditions, including the viability or sufficiency of his or her veins, be taken into consideration as part of the determination of the appropriate method of venous access.

103. The 2019 Protocol contains no requirement or provision ensuring Plaintiffs' access to counsel once the execution reaches the stage of setting the IVs, *see* Nov. 2019 Winter Dep. at

148:9-150:16, effectively preventing condemned prisoners from communicating to counsel any issues with the IV placement.

104. The 2019 Protocol also delegates critical decisions to personnel who lack and/or are not required to have appropriate background, experience, and training. The 2019 Protocol delegates to the BOP Director authority to determine the method of venous access for an execution with no requirement that he or she have adequate medical knowledge, experience, background, and training to make that critical medical decision. Although the 2019 Protocol allows the BOP Director to designate another person to determine the method of venous access, such designee is likewise not required to have adequate medical knowledge, experience, background, and training to make that critical decision.

105. Finally, the 2019 Protocol indicates that the determination of the method of venous access will be "(1) based on the training and experience of [the] personnel establishing the intravenous access; (2) to comply with specific orders of federal courts; or (3) based upon a recommendation from qualified personnel." 2019 Addendum, ¶ H. However, the 2019 Protocol does not require the personnel establishing the IV to have any minimum or particular "training [or] experience," and contains no limitation on who might be deemed to be "qualified personnel." The BOP has advised that Defendants intend to have an anesthesiologist and a nurse present at executions, and that the doctor will be responsible for setting IVs, with the assistance of the nurse. Both medical personnel are contractors, whose identities, qualifications, and experience the BOP has refused to disclose. These contractors have no contracts and will be paid in cash. *See* Nov. 2019 Winter Dep. at 184:6-191:9, 203:13-204:19, 208:13-209:13, 340:2-9. Given that the 2019 Protocol does not require that qualified medical personnel perform IV placement, there is no

guarantee that these contractors or any other medical professionals will in fact be present to perform this function at an execution.

106. That inadequate intravenous access presents a serious and avoidable risk of severe pain and suffering is confirmed by the fact that lethal-injection executions have frequently been plagued by difficulties with setting IVs that have caused serious harm to prisoners. The complaints in two other actions pending in this district, *Roane v. Gonzales*, No. 1:05-cv-02337-TSC (D.D.C. filed Dec. 6, 2005) (*Roane* Compl.), and *Bourgeois v. United States Dep't of Justice*, No. 1:12-cv-00782-TSC (D.D.C. filed May 15, 2012) (*Bourgeois* Compl.), provide details on the issues that have arisen. For example, kinked tubing and an improperly inserted IV needle caused one prisoner "excruciating pain" and delayed his execution, *Roane* Compl. ¶ 45(c), while another prisoner suffered a prolonged execution due to a clogged IV tube that could have been prevented by "proper procedures taught in 'IV 101,'" *id*. ¶ 45(f), and yet another prisoner "grimace[ed]," "tried to mouth words," and was not declared dead for 34 minutes as a result of a needle that improperly injected chemicals into his soft tissue, rather than into his vein, *Bourgeois* Compl. ¶ 59(k). Furthermore, difficulties in locating veins suitable for lethal injection have resulted in significant delays and other torment for prisoners awaiting execution. *See Roane* Compl. ¶ 46; *Bourgeois* Compl. ¶ 60.

107. There have been several recent, significant examples of IV problems in lethal injections. For example, at the well-publicized Clayton Lockett execution in 2014, the femoral line was not placed correctly and Mr. Lockett regained consciousness before dying. In addition, in Ohio (2017) and Alabama (2018), the execution teams tried unsuccessfully for an extended period of time to set IVs in two very ill prisoners, Alva Campbell and Doyle Lee Hamm. Those two executions were called off as a result.

108. The 2019 Protocol lacks detail and requirements to ensure intravenous access is properly established, functioning, maintained, and monitored throughout the entire execution process. Without those protections, the 2019 Protocol cannot be relied on to guarantee that executions using lethal injection will effectively bring about death in a humane and constitutional manner.

5. The 2019 Protocol Is Materially Incomplete.

109. As explained in detail above, although the 2019 Protocol provides some vague and high-level information, it lacks sufficient detail regarding the planned implementation of executions, including numerous factors that are necessary to ensure compliance with constitutional requirements.

110. In addition to the deficiencies detailed above (¶¶ 84-85, 88, 91, 95-97, 102-105, 108), the 2019 Protocol lacks sufficient detail and important requirements and safeguards regarding numerous other factors that are necessary to ensure lethal injection will effectively bring about death in a humane and constitutional manner, including, but not limited to, the following:

a. The 2019 Protocol does not require the presence of a doctor or anyone with a medical license to be present at or oversee the executions. *See* Nov. 2019 Winter Dep. at 171:8-174:21; *see also* Weinsheimer Dep. at 96:4-16, 100:6-101:7, 102:11-21.

b. The 2019 Protocol contains no criteria or requirements regarding the minimum qualifications and expertise required of the person who is given the responsibility and discretion to order the staff to divert from the established protocols if necessary to avoid inflicting severe and unnecessary pain and suffering, and the criteria to be used in exercising this discretion.

c. The 2019 Protocol contains no criteria or requirements regarding the minimum qualifications and expertise required of the person who is given the responsibility and discretion to ensure that appropriate procedures are followed in response to unanticipated problems or events arising during the execution, and the criteria that shall be used in exercising this discretion.

d. The 2019 Protocol expressly blocks access to information about the qualifications of personnel, stating that "any documentation establishing [the] qualifications" of the personnel involved in the executions "shall be protected from disclosure to the fullest extent permitted by law." 2019 Addendum, ¶ B.

111. Moreover, the 2019 Protocol provides that "[t]hese procedures should be observed and followed as written unless deviation or adjustment is required, as determined by the Director of the BOP or the Warden." AR 1019. The 2019 Addendum similarly provides as follows:

> The procedures utilized by the BOP to implement federal death sentences shall be as follows unless modified at the discretion of the Director or his/her designee, as necessary to (1) comply with specific judicial orders; (2) based on the recommendation of on-site medical personnel utilizing their clinical judgment; or (3) as may be required by other circumstances.

2019 Addendum, ¶ A. However, the 2019 Addendum does not contain any detail or requirements concerning the "other circumstances" which allow for deviation from the stated execution procedures.

112. The 2019 Protocol is materially incomplete and lacks sufficient detail, requirements, and safeguards regarding the implementation of executions. Without those protections, the 2019 Protocol cannot be relied on to guarantee that executions using lethal injection will effectively bring about death in a humane and constitutional manner.

C. Alternatives Relating to Eighth Amendment Issues

113. The United States Supreme Court has held that in order to establish an Eighth Amendment violation, "a prisoner must show a feasible and readily implemented alternative method of execution that would significantly reduce a substantial risk of severe pain and that the State has refused to adopt without a legitimate penological reason." *Bucklew v. Precythe*, 139 S. Ct. 1112, 1125 (2019).

114. Based on statutory authority and current and historical practices, upon information and belief, the following alternative methods of execution are feasible and readily implemented and available and would significantly reduce a substantial risk of severe pain which Defendants have refused to adopt without a legitimate penological reason.[1]

a. Execution by a single dose of FDA-approved pentobarbital, including implementing the remedial measures and safeguards detailed below and adding a pre-dose of a pain-relieving, anesthetic drug in a sufficiently large clinical dose. There are a wide variety of well-known, accessible, and easily administered pain-relieving medications used in anesthetic procedures. *See* Van Norman Decl. at 7, 18-19, 29-30; Decl. of Craig W. Stevens, Ph.D. at 2-7 (Nov. 1, 2019), ECF No. 25. The opioid fentanyl is one option of a drug that would substantially reduce the risk that the prisoner would remain sensate to experience pain, including the pain and

[1] Plaintiffs Battle, Paul, Purkey, and Webster are unable or incompetent to consult with counsel concerning alternative methods of execution. Allegations concerning alternative methods of execution with respect to those Plaintiffs are pled solely by counsel acting on their behalf. Mr. Battle has suffered for decades from schizophrenia and has more recently been diagnosed with vascular dementia in his temporal and frontal lobes, a severe and degenerative neurological disease that has stripped Mr. Battle of his memory and other mental functions. Mr. Purkey's competency to be executed is at issue in separate litigation pending before this Court, *see Purkey v. Barr*, No. 1:19-cv-03570 (D.D.C. filed Nov. 26, 2019). Plaintiffs Battle, Paul, Purkey, and Webster are therefore relieved of the obligation to plead alternative methods of execution to state an Eighth Amendment claim, *see In re Ohio Execution Protocol Litigation*, No. 2:11-cv-1016, 2018 WL 3207419, at *2 (S.D. Ohio June 29, 2018) ("A fortiori, a person incompetent to be executed is also incompetent to stand trial and also to properly consult with his attorney about pleading an alternative method of execution."); *see also Walton v. Johnson*, 318 F. Supp. 2d 345, 349 (W.D. Va. 2004) ("Although no court has yet articulated the standard of competency to select a method of execution, the court finds the standard does not differ significantly from the standard for competency to be executed."), *aff'd*, 440 F.3d 160 (4th Cir. 2006) (en banc).

suffering caused by pulmonary edema. The BOP has asserted that "numerous companies manufacture" fentanyl and that brand-name and generic products are sold in the United States. AR 862-63. The BOP also has confirmed that it has located a lawfully licensed compounding pharmacy in the United States that is able and willing to "lawfully provide [BOP] with commercially manufactured medications as they are available," and to compound fentanyl as needed. *Id.* at 864. The necessary remedial measures and safeguards are as follows:

i. the selection of qualified, competent and vetted team members, whose qualifications are disclosed;

ii. establishment of two patent, functioning peripheral IV lines and assurance (a) that no central line will be placed unless it is determined to be necessary following a vein assessment by a qualified medical professional, and (b) central lines will be set only by qualified and competent medical professionals; and

iii. the administration of pentobarbital in close proximity to the prisoner, rather than remotely. Eliminating the need for extension sets of IV tubing can significantly reduce the risks of leakage or pinching of the tubing. Proximate administration would also ensure adequate surveillance and monitoring of the IV, the catheter site, and the prisoner. By eliminating the need for lengthy IV tubing, proximate administration would greatly reduce the variation and risk introduced by the increased contact, and subsequent resistance, between the drug and the walls of the tubing. Any concern about revealing the identity of personnel participating in the execution process could be satisfactorily addressed by using a privacy screen.

b. Execution by a single dose of compounded pentobarbital that complies with all state and federal compounding requirements, and has been tested for purity and potency, with records of testing, chain of custody, and compounding formula disclosed to prisoners and their counsel, including a pre-dose of a pain-relieving, anesthetic drug in a sufficiently large clinical dose, and implementing the remedial measures and safeguards set forth in paragraph 114(a)(i)-(iii) above.

c. Execution by firing squad. Execution by firing squad is a method of execution currently authorized by the laws of three states (Utah, Oklahoma, Mississippi) which Defendants

have the means and ability to administer. Execution by firing squad eliminates entirely the risk of pain and suffering inherent in executions using pentobarbital and the procedures set forth in the 2019 Protocol, including risks associated with establishing IV access and addressing prisoner's unique physical, health, and medical conditions. Execution by firing squad causes a faster and less painful death than execution by lethal injection. *See Arthur v. Dunn*, 137 S. Ct. 725, 733-34 (2017) (Sotomayor, J., dissenting) (citing reports and stating that a firing squad may cause nearly instantaneous death, be comparatively painless, and have a lower chance of a botched execution); *see also Bucklew*, 139 S. Ct. at 1136 (Kavanaugh, J., concurring) (addressing the availability of firing squad as an alternative). Execution by firing squad also "is significantly more reliable" than lethal injection. *Glossip v. Gross*, 135 S. Ct. 2726, 2796 (2015) (Sotomayor, J., dissenting). Recent studies have confirmed that execution by firing squad statistically is much less likely to result in "botched" executions than lethal injection. *See* AUSTIN SARAT, GRUESOME SPECTACLES: BOTCHED EXECUTIONS AND AMERICA'S DEATH PENALTY 120, App. A (2014) (analysis of contemporaneous news reports of all executions in the United States from 1900 to 2010 found that 7.12% of the 1,054 executions by lethal injection were "botched" and none, 0%, of the 34 executions by firing squad were "botched").

V. Exhaustion of Administrative Remedies

115. Each of the Plaintiffs has either exhausted all available administrative remedies, believes exhaustion is not necessary under the Prison Litigation Reform Act, 42 U.S.C. § 1997e (because this suit does not challenge prison conditions, and because there are no available administrative remedies that could address the challenged constitutional violations), or the Defendants have agreed not to assert failure to exhaust administrative remedies as a defense in this action.

VI. Claims for Relief

Count I
(Fifth Amendment Violation — Denial of Due Process)

116. Plaintiffs reallege and incorporate herein by reference all of the preceding paragraphs of the Amended Complaint as if set forth in full below.

117. The Due Process Clause of the Fifth Amendment of the U.S. Constitution requires notice and an opportunity to be heard before the deprivation of life, liberty, or property.

118. Being "deprived of life" unequivocally implicates a constitutionally protected interest, U.S. Const. amend. V, and the U.S. Supreme Court has held that constitutionally protected "liberty interests are implicated" when the government plans to "inflict[] appreciable physical pain," *Ingraham v. Wright*, 430 U.S. 651, 674 (1977).

119. Defendants, acting under color of federal law, have not disclosed sufficient information or details regarding the development and drafting of the 2019 Protocol or the procedures that will be utilized in carrying out Plaintiffs' executions pursuant to the 2019 Protocol, thereby preventing Plaintiffs from determining all aspects of the 2019 Protocol that violate provisions of federal law or constitute cruel and unusual punishment, and from consulting medical experts concerning those aspects, and preventing Plaintiffs from determining and seeking to remedy the ways in which the 2019 Protocol presents an avoidable risk of pain and suffering during their executions.

120. In addition, the discretion given to the BOP Director under the 2019 Protocol to change the implementation of death sentences means that Plaintiffs will not have sufficient notice and opportunity to challenge the manner of their executions.

121. Executing Plaintiffs pursuant to the 2019 Protocol would violate the Due Process Clause of the Fifth Amendment of the U.S. Constitution because it would deprive Plaintiffs of

their lives and liberty without providing sufficient notice and opportunity to be heard on the execution procedures to be used.

Count II
(Eighth Amendment Violation — Cruel and Unusual Punishment)

122. Plaintiffs reallege and incorporate herein by reference all of the preceding paragraphs of the Amended Complaint as if set forth in full below.

123. The Eighth Amendment of the U.S. Constitution forbids the Government, in carrying out a death sentence, from inflicting pain beyond that necessary to end the condemned prisoner's life. *See In re Kemmler*, 136 U.S. 436, 447 (1890). "Punishments are cruel when they involve torture or a lingering death . . . something more than the mere extinguishment of life." *Id.; see also Baze v. Rees*, 553 U.S. 35, 50 (2008) (execution violates the Eighth Amendment if it presents a "substantial risk of serious harm").

124. Defendants, acting under color of federal law, intend to execute Plaintiffs in a manner that is arbitrary, cruel, and/or unreliable, and which will inflict excruciating pain on Plaintiffs, or has a foreseeable and significant but completely avoidable and unnecessary risk of causing such pain.

125. There are alternative methods of execution, as described above, that are "feasible, readily implemented, and in fact [would] significantly reduce the substantial risk of severe pain." *Baze*, 553 U.S. at 52.

126. Because the 2019 Protocol poses a substantial risk of serious harm to Plaintiffs, it violates Plaintiffs' constitutional right guaranteed by the Eighth Amendment of the U.S. Constitution to be free from arbitrary, capricious, cruel, and unusual punishment.

Count III
(Eighth and Fifth Amendment Violation — Deliberate Indifference)

127. Plaintiffs reallege and incorporate herein by reference all of the preceding paragraphs of the Amended Complaint as if set forth in full below.

128. The Eighth Amendment forbids "deliberate indifference" to "serious medical needs of prisoners," *Estelle v. Gamble*, 429 U.S. 97, 104 (1976), and to a substantial risk of serious harm to a prisoner. *See Farmer v. Brennan*, 511 U.S. 825, 834 (1994).

129. Substantive Due Process affords similar protections: "[A] physician who acts on behalf of the State to provide needed medical attention to a person involuntarily in state custody (in prison or elsewhere) and prevented from otherwise obtaining it, and who causes physical harm to such a person by deliberate indifference, violates the [Constitution's] protection against the deprivation of liberty without due process." *West v. Atkins*, 487 U.S. 42, 58 (1988) (Scalia, J., concurring).

130. The BOP undertakes to provide inmates with five major levels of medical care, including emergency care and "medically necessary" care, which is defined as treatment "without [which] care an inmate could not be maintained without significant risk of . . . [s]erious deterioration leading to premature death[;] [s]ignificant reduction in the possibility of repair later without present treatment[;] or [s]ignificant pain or discomfort which impairs the inmate's participation in activities of daily living." U.S. Dep't of Justice, Fed. Bureau of Prisons, Program Statement No. 6031.04, § 7 (June 3, 2014).

131. The choice of a course of medical treatment may violate the Eighth Amendment where it is "so blatantly inappropriate as to evidence intentional mistreatment likely to seriously

aggravate the prisoner's condition." *Thomas v. Pate*, 493 F.2d 151, 158 (7th Cir. 1974), *vacated and remanded on other grounds sub nom. Cannon v. Thomas*, 419 U.S. 813 (1974).

132. The Attorney General and the BOP Defendants are required to provide Plaintiffs with appropriate medical care until the moment of their deaths. Thus, the Eighth Amendment's proscription against "deliberate indifference" requires that they administer the death penalty without the "unnecessary and wanton infliction of pain." *Gregg v. Georgia*, 428 U.S. 153, 173 (1976).

133. The means chosen by the Attorney General and the BOP Defendants to execute Plaintiffs under the 2019 Protocol constitute deliberate indifference to a substantial risk of serious harm to Plaintiffs. Plaintiffs have alleged several feasible and readily implemented alternatives to the 2019 Protocol that would substantially reduce the substantial harm to Plaintiffs.

134. The 2019 Protocol violates rights secured and guaranteed to Plaintiffs by the Fifth and Eighth Amendments of the U.S. Constitution.

Count IV
(First, Fifth and Sixth Amendment Violations — Access to Counsel)

135. Plaintiffs reallege and incorporate herein by reference all of the preceding paragraphs of the Amended Complaint as if set forth in full below.

136. Prisoners have a right under the First and Fifth Amendments of the U.S. Constitution to access to the courts. *See, e.g., Lewis v. Casey*, 518 U.S. 343, 350-51 (1996); *Wolff v. McDonnell*, 418 U.S. 539, 579 (1974).

137. Prisoners also have a right under the Sixth Amendment of the U.S. Constitution to access to counsel at all "critical" stages of criminal proceedings. *United States v. Wade*, 388 U.S. 218, 227-28 (1967).

138. Prisoners have the right to access to counsel throughout the execution procedure, including during an execution. *See Harbison v. Bell*, 556 U.S. 180, 194 (2009); *In re Ohio Execution Protocol Litig.*, No. 2:11-cv-1016, 2018 WL 6529145, at *4-5 (S.D. Ohio Dec. 12, 2018).

139. To assert an Eighth Amendment violation prior to or during an execution, Plaintiffs must be able to communicate that violation to their counsel, and counsel must be able to access the courts on the Plaintiffs' behalf. Abridgement of either prisoner-counsel communication or counsel's access to the courts violates Plaintiffs' constitutional right to access to counsel and the courts.

140. The 2019 Protocol does not provide Plaintiffs with access to counsel during an execution. Therefore, under the 2019 Protocol, Plaintiffs will not be able to communicate with their counsel prior to and during the execution and will not be able to communicate with counsel regarding any problems, including constitutional violations.

141. In addition, the 2019 Protocol does not permit witnesses (including Plaintiffs' attorneys or medical consultants) to view the setting of IVs, so there is no way to identify, object to, challenge, or correct any issues with the IV-setting process, including constitutional violations.

142. The 2019 Protocol's deprivation of access to counsel and the courts prior to and during the execution violates Plaintiffs' rights under the First, Fifth, and Sixth Amendments.

Count V
(Violation of APA — *Ultra Vires* Agency Action Contrary to the FDPA and U.S. Constitution)

143. Plaintiffs reallege and incorporate herein by reference all of the preceding paragraphs of the Amended Complaint as if set forth in full below.

144. The APA requires a reviewing court to set aside any agency action that is "not in accordance with [the] law," "in excess of statutory jurisdiction, authority, or limitations," or "contrary to constitutional right, power, privilege or immunity." 5 U.S.C. § 706(2)(A)-(C).

145. The Take Care Clause of the U.S. Constitution imposes a duty on the Executive Branch to "take Care that the Laws be faithfully executed." U.S. Const., art. II, § 3. The Take Care Clause forbids the Executive Branch from making acts of Congress unlawful by refusing to enforce them as written. The Take Care Clause preserves the principles of separation of powers inherent in the U.S. Constitution by preventing the Executive Branch from arrogating to itself the legislative power to revoke or rewrite laws.

146. The 2019 Protocol violates Section 3596 of the FDPA. The 2019 Protocol does not require executions to be "implement[ed] . . . in the manner prescribed by the law of the State in which the sentence is imposed," 18 U.S.C. § 3596(a), but, rather, purports to implement a protocol that differs in material respects from the applicable states. *See* Appendix A attached hereto. Upon information and belief, Defendants will utilize the 2019 Protocol in any execution instead of the manner deemed binding by the law of each State where Plaintiffs were sentenced. In the alternative and assuming that there is a finding that Defendants have the discretion to deviate from the 2019 Protocol in order to implement executions in the manner prescribed by the laws of the States, Defendants have failed to provide notice of which States' procedures they will follow and what changes they will make to comply with the binding law of those States.

147. The 2019 Protocol does not require "a United States marshal [to] supervise implementation of the sentence" as required by 18 U.S.C. § 3596(a). *See* Sheehan Dep. at 41:6-42:2. Rather, the 2019 Protocol purports to delegate that responsibility to the Director of the BOP. The USMS had no meaningful role in the preparation of the 2019 Protocol and its role in

federal executions is limited to identifying impediments, such as pardons or stays, and then "giv[ing] the approval to the Bureau of Prisons to carry out the execution." *Id.*

148. The 2019 Protocol illegally contravenes Congressional intent insofar as it purports to prescribe the manner for execution of prisoners, including Plaintiffs, who are sentenced to death under the FDPA. The 2019 Protocol therefore constitutes *ultra vires* agency action because the DOJ and the BOP lacked the authority under the FDPA to issue the 2019 Protocol, and also violates the Take Care Clause of the Constitution and the principles of separation of powers.

149. Accordingly, the 2019 Protocol should be held unlawful and set aside pursuant to the APA, 5 U.S.C. § 706(2).

Count VI
(Violation of the APA — Violation of Notice-and-Comment Rulemaking)

150. Plaintiffs reallege and incorporate herein by reference all of the preceding paragraphs of the Amended Complaint as if set forth in full below.

151. The APA requires a reviewing court to set aside any agency action taken "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

152. The APA required the DOJ and the BOP to provide adequate advance notice of the proposed 2019 Protocol, a full and fair opportunity for public comment, and an explanation of the rule ultimately adopted. *See* 5 U.S.C. § 553(b), (c).

153. The DOJ and the BOP failed to provide advance notice or opportunity for the public to comment on the 2019 Protocol prior to its promulgation, as well as an adequate explanation for the protocol's issuance. In issuing the 2019 Protocol in contravention of such procedural requirements, the DOJ and the BOP violated the APA.

154. The DOJ's and the BOP's violation of the APA caused harm to Plaintiffs by depriving them and the public of the right and opportunity to consider and address issues and concerns with the 2019 Protocol, including, but not limited to, Defendants' failure to provide adequate notice of the procedures to which Plaintiffs would be subjected; the protocol's failure to protect Plaintiffs' right of access to counsel and the courts; and the risk of an unavoidably painful execution—including the risk of cruel and unusual punishment under the Eighth Amendment—on account of the properties of pentobarbital, the undefined and unrestricted procedures to be used in executions, and/or the absence of sufficient safeguards.

155. Accordingly, the 2019 Protocol should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2).

Count VII
(Unconstitutional Delegation of Legislative Power)

156. Plaintiffs reallege and incorporate herein by reference all of the preceding paragraphs of the Amended Complaint as if set forth in full below.

157. Article I, Section 1 of the United States Constitution vests "[a]ll legislative Powers" in Congress and bars the delegation of legislative power.

158. If it is determined that Section 3596, which directs that the U.S. Marshal "shall supervise implementation of the sentence in the manner prescribed by the law of the State in which the sentence is imposed," authorizes the Attorney General to implement the sentence under a federal protocol, then the statute has failed to provide "an intelligible principle to which the person or body authorized . . . is directed to conform," and thus constitutes "a forbidden delegation of legislative power." *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928); *see also* 18 U.S.C. § 3596(a).

Count VIII
(Violation of the APA — Arbitrary and Capricious Agency Action)

159. Plaintiffs reallege and incorporate herein by reference all of the preceding paragraphs of the Amended Complaint as if set forth in full below.

160. The APA requires a reviewing court to set aside any agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

161. Agency action that is not the product of reasoned decision-making is arbitrary and capricious. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). To satisfy the requirement of reasoned decision-making, an agency must "cogently explain why it has exercised its discretion in a given manner." *Id*. at 48.

162. An agency's rule is also arbitrary and capricious when, among other circumstances, the agency has "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43.

163. Neither the DOJ nor the BOP provided any explanation for the basis or reasons for the decision to adopt the 2019 Protocol or the procedures contained therein. In particular, neither the DOJ nor the BOP has adequately considered or provided any explanation or justification for their planned use of pentobarbital as an execution drug, their failure to comply with applicable laws, including the CSA and FDCA, or the absence of necessary safeguards to protect against the significant risk of pain and suffering that the use of pentobarbital will cause to Plaintiffs, including the risk of acute pulmonary edema and the harm caused by the use of sub-potent or improperly compounded drugs.

164. The adoption of the 2019 Protocol was not the product of reasoned decision-making and entirely failed to consider important aspects of the problem, and is thus arbitrary and capricious, in violation of the APA.

165. The DOJ's and the BOP's violation of the APA caused harm to Plaintiffs by depriving them of the right and opportunity to consider and address issues and concerns with the 2019 Protocol, including, but not limited to, Defendants' failure to provide adequate notice of the procedures to which Plaintiffs would be subjected; the protocol's failure to protect Plaintiffs' right of access to counsel and the courts; and the risk of an unavoidably painful execution, including the risk of cruel and unusual punishment under the Eighth Amendment on account of the properties of pentobarbital, the undefined and unrestricted procedures to be used in executions, and/or the absence of sufficient safeguards.

166. Accordingly, the 2019 Protocol should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2).

Count IX
(Violation of the APA — Arbitrary and Capricious Failure to Exercise Enforcement Authority under the CSA)

167. Plaintiffs reallege and incorporate herein by reference all of the preceding paragraphs of the Amended Complaint as if set forth in full below.

168. The CSA makes it unlawful to "dispense" any "controlled substance," 21 U.S.C. § 841(a)(1), except pursuant to a valid prescription "issued for a legitimate medical purpose" by a practitioner who is "acting in the usual course of professional practice" and registered pursuant to the statute. 21 U.S.C. §§ 802(21), 829(e)(2).

169. Regulations promulgated by the DEA provide that every person who "dispenses" a "controlled substance" is required to obtain a registration. 21 C.F.R. § 1301.11. The regulations

also provide that the DEA Administrator "shall deny" an application for registration unless the issuance of a registration is "required" under the CSA. 21 C.F.R. § 1301.35.

170. Pentobarbital is a Schedule II controlled substance. 21 C.F.R. § 1308.12(e)(3).

171. The 2019 Protocol violates the CSA because it requires the dispensing and administration of pentobarbital without a valid prescription, for use that is not a legitimate medical purpose, and by persons who are not acting in the course of professional practice and/or lack a valid registration.

172. Defendant Shea has arbitrarily and capriciously failed to exercise his authority to enforce the CSA by not requiring the persons who will dispense the pentobarbital to apply for a registration, and will continue to act arbitrarily and capriciously by permitting them to dispense the pentobarbital without obtaining such registration or without obtaining a valid medical prescription.

173. Such arbitrary and capricious action violates the APA.

174. This violation of the APA causes harm to Plaintiffs because, as alleged above, an execution under the 2019 Protocol—with the use of pentobarbital in violation of the CSA—has the substantial probability of resulting in cruel and unusual punishment due to the properties of pentobarbital.

175. Accordingly, the 2019 Protocol should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2)(A).

Count X
(Violation of the APA —
Arbitrary and Capricious Failure to Exercise
Enforcement Authority Under the FDCA)

176. Plaintiffs reallege and incorporate herein by reference all of the preceding paragraphs of this Amended Complaint as if set forth in full below.

177. The FDCA's "core" legislative purpose is to ensure that a drug is "'safe' and 'effective' for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).

178. The FDCA conditions dispensing of FDA-approved drugs such as pentobarbital upon either (a) "a written prescription of a practitioner licensed by law to administer such drug," or (b) "an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist." 21 U.S.C. § 353(b)(1).

179. Under the FDCA, the proposed dispensing and administration of compounded pentobarbital requires a valid medical prescription reflecting a medical practitioner's order that "a compounded product is necessary for the identified patient." 21 U.S.C. § 353a(a).

180. Upon information and belief, Defendants have not obtained medical prescriptions to use either FDA-approved or compounded pentobarbital in connection with executions of Plaintiffs.

181. The 2019 Protocol violates the FDCA by allowing the dispensing, administration, and use of pentobarbital and/or compounded pentobarbital without a valid medical prescription. *See* 21 U.S.C. §§ 353(b)(1), 353a(a), 353a(b)(1)(D), 353a(b)(2), 353b(a)(5), and 353b(d)(2).

182. Defendant Hahn has acted in an arbitrary and capricious manner by failing to exercise his authority to enforce the FDCA by not requiring the persons who will dispense the pentobarbital to have a valid registration. Defendant Hahn will continue to act arbitrarily and capriciously by permitting these persons to dispense the pentobarbital without a proper registration and without obtaining a valid medical prescription.

183. Such arbitrary and capricious action violates the APA.

184. This violation of the APA causes harm to Plaintiffs because, as alleged above, an execution under the 2019 Protocol—with the use of pentobarbital in violation of the FDCA—

has the substantial probability of resulting in cruel and unusual punishment due to the properties of pentobarbital.

185. Accordingly, the 2019 Protocol should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2)(A).

Count XI
Violation of the APA –
Agency Action that is Contrary to Law
Because it Violates the FDCA and CSA

186. Plaintiffs reallege and incorporate herein by reference all of the preceding paragraphs of this Amended Complaint as if set forth in full below.

187. Under the APA, a reviewing court must set aside any agency action that is "not in accordance with [the] law," or is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A) and (C).

188. As explained above, the 2019 Protocol violates both the CSA and the FDCA.

189. The APA provides a private right of action when, as here, an agency's action is "not in accordance with [the] law," 5 U.S.C. § 706(2)(A), and regardless of whether those two underlying statutes provide a right of action by themselves. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 317-18 (1979).

190. Defendants' violations of the federal drug laws will cause injury to Plaintiffs by circumventing the statutory purposes of the CSA and FDCA to ensure that all drugs, including those used to carry out an execution, are safe and effective and dispensed and administered properly. *See FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 133 (2000). "[I]gnoring those safeguards, as Plaintiffs allege Defendants intend to do, places Plaintiffs at risk." *Ringo v. Lombardi*, 706 F. Supp. 2d 952, 958 (W.D. Mo. 2010); *see also id.* at 962; *Beaty v. FDA*, 853 F. Supp. 2d 30, 42-43 (D.D.C. 2012) (explaining that importation of a misbranded

execution drug implicates the FDCA's statutory purposes, including the need to ensure that a drug is safe and effective: "Even when in the correct hands, prisoners on death row have an unnecessary risk that they will not be anesthetized properly prior to execution."), *aff'd in part, vacated in part sub nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013).

191. Accordingly, the 2019 Protocol should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2).

VII. Prayer for Relief

WHEREFORE, in order to prevent the violations of Plaintiffs' rights under the First, Fifth, Sixth, and Eighth Amendments of the U.S. Constitution, and the violations of the APA, the FDPA, the FDCA, and CSA alleged above, Plaintiffs respectfully request that the Court enter a judgment:

a. declaring that the Defendants' actions, practices, customs, and policies with regard to their means, methods, procedures, and customs regarding executions, and specifically the 2019 Protocol, are illegal and violate the First, Fifth, Sixth and Eighth Amendments of the U.S. Constitution, the APA, the FDPA, the FDCA, and the CSA;

b. vacating the 2019 Protocol and enjoining Defendants and all persons acting on their behalf from using the 2019 Protocol, or any revised protocol that violates Plaintiffs' rights and the law, for the same reasons challenged above;

c. granting Plaintiffs their reasonable attorneys' fees pursuant to 42 U.S.C. § 1988 and the laws of the United States; and

d. granting such further relief as the Court deems just and proper.

Dated: June 1, 2020

Respectfully submitted,

/s/ Alan E. Schoenfeld

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Appendix A

Appendix A: Representative Differences Between State and Federal Execution Procedures[1]

State	State Requirement	Federal Requirement
Arkansas	The Arkansas Department of Corrections is statutorily mandated to promulgate a lethal injection drug protocol from one of two options: "[a] barbiturate," or "[m]idazolam, followed by vecuronium bromide, followed by potassium chloride." Ark. Code § 5-4-617(c). Pursuant to its delegated authority, the Arkansas Department of Corrections adopted a protocol using the three-drug formula allowed by statute. Arkansas Protocol § III.5; *see* Ark. Code § 5-4-617(c).	The BOP's 2019 Protocol mandates that executions be carried out using Pentobarbital Sodium. 2019 Addendum, ¶ C; AR at 1069.
	The drugs "used to carry out the lethal injection shall be . . . [a]pproved by the United States Food and Drug Administration and made by a manufacturer approved by the United States Food and Drug Administration," "[o]btained from a facility registered with the United States Food and Drug Administration," or "[o]btained from a compounding pharmacy that has been accredited by a national organization that accredits compounding pharmacies." Ark. Code § 5-4-617(d).	The 2019 Protocol is silent about requirements for the provenance and form of execution drugs to be used and requires no assurances regarding the entities that provide the drug.
	"Catheters, sterile intravenous solution, and other equipment" used in executions "be sterilized and prepared in a manner that is safe and commonly performed in connection with the intravenous administration of drugs of that type." Ark Code § 5-4-617(f).	The 2019 Protocol is silent about the equipment to be used in executions.
	"Each member of the IV team shall have at least two . . . years of professional experience and certification or licensure" as an EMT-intermediate, EMT-paramedic, nurse, physician assistant, or physician. Arkansas Protocol § V.	The 2019 Protocol requires that "medically trained personnel" have only "one year professional experience." 2019 Addendum, ¶ D; AR at 1069.
	The Arkansas protocol directs that a peripheral IV line "shall" be placed "in each arm." Arkansas Protocol § II.1. If the IV Team is not able to establish patent IV infusion sites, then it may evaluate other possible infusion sites. If the IV Team is unable to establish IV access, "trained, educated, and experienced person(s)" will be brought in to establish a peripheral or central line IV. *Id.* at II.8. The Arkansas protocol allows use of lidocaine during IV placement. *Id.* at II.	The 2019 Protocol is silent about preferred IV access sites, thus allowing placement of a central line – or even a cutdown procedure – before exploration of peripheral access sites.

[1] This Appendix contains a representative sample of differences between the federal lethal-injection Protocol (the 2019 Protocol) and the laws, regulations, and execution protocols "prescribed by the law of the State in which [Plaintiffs'] sentence[s are] imposed." 18 U.S.C. § 3596. Plaintiffs reserve the right to argue that the federal government must adhere to additional requirements "prescribed by" other portions of "the law of the State." *See id.* Upon information and belief, all of the protocols cited in this Appendix are publicly available, with the exception of South Carolina's. *See, i.e.* https://deathpenaltyinfo.org/executions/lethal-injection/state-by-state-lethal-injection-protocols (last visited 6/1/20).

Georgia	"There shall be present at the execution of a convicted person the superintendent of the state correctional institution or a deputy superintendent thereof, at least three executioners, [and] two physicians to determine when death supervenes . . . ." Ga. Code § 17-10-41.	The BOP's 2019 Protocol does not require the presence of physicians. 2019 Addendum, ¶ D; AR at 1069.
	The IV Team, which obtains IV access, must contain at least one nurse. GDOC Protocol § I.A; AR at 9. The nurse also attaches a heart monitor to the prisoner. GDOC Protocol § II.D.4; AR at 12.	The 2019 Protocol does not require the presence of nurses. 2019 Addendum, ¶ D; AR at 1069.
	"Within one hour of execution, … The condemned will be offered a mild sedative by a Physician." GDOC Protocol § II.C.4; AR at 11.	The 2019 Protocol does not provide for pre-treatment.
	The Georgia protocol expresses a clear preference for peripheral venous access. Central line access is a last resort, and central venous access must be obtained by a physician. GDOC Protocol § II.D.3; AR at 12.	The 2019 Protocol tasks the Director with determining venous access and does not require that a physician establish central vein access. 2019 Addendum, ¶ G; AR at 1070.
	The Georgia protocol requires that a nurse "monitor the progress of the injection" throughout the execution "to ensure proper delivery of chemicals and to monitor for any signs of consciousness." If the nurse observes a problem with the flow of the drugs through the IV, "the Nurse will inform the attending Physician," who advises the Warden whether it is necessary to change to the second IV. GDOC Protocol § II.E.3; AR at 13.	The 2019 Protocol does not require the presence of nurses or physicians, nor does it require a medical professional to monitor the drug administration.
	The Georgia protocol provides a contingency plan in the event that the prisoner is not deceased following administration of 5 grams of pentobarbital. GDOC Protocol § II.E.4; AR at 13.	The 2019 Protocol does not contain a contingency plan in the event the prisoner is alive after administration of 5 grams of pentobarbital.
Indiana	"The death penalty shall be inflicted before the hour of sunrise on a date fixed by the sentencing court." Ind. Code § 35-38-6-1.	The BOP's 2019 Protocol does not specify a pre-dawn execution time.
	The Indiana Department of Corrections administers a three-drug protocol: Brevital (methohexital sodium), Pancuronium or Vecuronium Bromide, and Potassium Chloride. IDOC Protocol Injection Process, p. 15; *see also* Death Penalty in Indiana, https://www.in.gov/idoc/3349.htm (specifying IDOC's current use of Brevital) (last visited 5/30/20).	The 2019 Protocol mandates that executions be carried out using Pentobarbital Sodium. 2019 Addendum, ¶ C; AR at 1069.
	A physician "shall . . . be present at the State Prison at the time of the execution; an alternate physician will also be notified and available in the event the primary physician is unable to be at the facility." IDOC Protocol, p. 5.	The 2019 Protocol does not require the presence of physicians. 2019 Addendum, ¶ D; AR at 1069.
	"After four . . . attempts for intravenous access," the IV team shall leave the room, and the physician shall perform a venous cut down. IDOC Protocol Appendix A.	The 2019 Protocol tasks the Director with determining venous access and does not require that a physician establish central vein access. Addendum, ¶ G; AR at 1070.

	The Indiana protocol requires that procurement of execution drugs be "in accordance with the Indiana Board of Pharmacy Controlled Substance Registration Certification and the Drug Enforcement Administration Controlled Substance Registration Certification." The protocol also specifies that "refrigeration logs will be maintained" and that expired drugs will be used for training purposes only and will be destroyed. IDOC Protocol Appendix B.	The 2019 Protocol does not require that procurement of execution drugs comply with state or federal law, does not speak to storage of the compounded drugs and does not prohibit use of expired drugs.
Missouri	"The manner of inflicting the punishment of death shall be by the administration of lethal gas or by means of the administration of lethal injection." Mo. Rev. Stat. 546.720(1).	The BOP's 2019 Protocol mandates that executions be carried out by lethal injection. 2019 Addendum ¶ C; AR at 1069.
	The "execution team" includes a physician, nurse, and pharmacist. MDOC Protocol at ¶A; AR at 70.	The 2019 Protocol does not require the presence of a physician, nurse or pharmacist.
	Missouri's protocol requires the preparation of two doses of 5 grams of pentobarbital. The executioners administer the second dose if the prisoner isn't deceased after the first dose and a consciousness check. MDOC Protocol at ¶ E4; AR at 71.	The 2019 Protocol does not provide a plan in the event the prisoner is not dead after administration of 5 grams of pentobarbital.
	The Missouri protocol states a presumption in favor of peripheral IV access, calling for establishment of a primary or secondary IV line. The primary line can be peripheral or central (femoral or subclavian veins), but only if the medical personnel's training includes central vein access. The secondary line is to be peripheral. MDOC Protocol at ¶ C.1; AR at.71.	The 2019 Protocol does not state a preference for peripheral access and does not require the presence of a physician to establish central line access.
	Missouri's procedures provide that the prisoner be offered a sedative in advance of the execution. *See Ringo v. Lombardi*, No. 2:09-cv-4095 (W.D. Mo. Jan. 21, 2011), Dist. Dkt. #210-7 (Missouri "Chronological Sequence of Execution").	The 2019 Protocol does not provide for pre-treatment.
South Carolina	Condemned prisoners may choose between electrocution and lethal injection. The default execution method is electrocution; lethal injection is only used when chosen by the condemned prisoner. S.C. Code § 24-3-530(A).	The BOP's 2019 Protocol mandates that executions be carried out by lethal injection. 2019 Addendum ¶ A; AR at 1069.
	South Carolina's lethal injection protocol calls for administration of a different drug formula than that laid out in the BOP's 2019 Protocol. Upon information and belief, South Carolina's current protocol calls for serial administration of thiopental, a paralytic and potassium chloride. https://deathpenaltyinfo.org/executions/lethal-injection/state-by-state-lethal-injection-protocols (last visited 6/1/20).	The 2019 Protocol mandates that executions be carried out by Pentobarbital Sodium. 2019 Addendum ¶ C; AR at 1069.

Texas	Executions shall take place "at any time after the hour of 6 p.m. on the day set for the execution." Tex. Code of Crim. Proc. Art. 43.14(a).	The BOP's 2019 Protocol does not specify a post-6 p.m. execution time.
	Texas's protocol specifies a preference for peripheral vein access, directing the medically-trained team member to look for a vein in the inmate's arm. If a suitable vein cannot be located in the arm, the medically-trained team member is directed to then look for a vein in a different part of the body, but "shall not use a 'cut-down' procedure to access a suitable vein." TDCJ Protocol § VII.C; AR at 90.	The 2019 Protocol does not specify an order for preferred IV access sites, does not default to peripheral access and does not prohibit use of a cut-down procedure.
	The Texas protocol provides that after the first syringe of pentobarbital is administered, if there are still signs of life, the Director or designee can authorize a second injection of 5 grams of pentobarbital. TDCJ Protocol § VII.J; AR at 91.	The 2019 Protocol contains no contingency plan in the event the prisoners shows signs of life following administration of 5 grams of pentobarbital.
	The Texas protocol requires the presence of a physician, who will examine the prisoner after administration of the lethal injection and pronounce death. TDCJ Protocol §VII.K; AR at 91.	The 2019 Protocol does not require the presence of a physician and does not specify who declares death or how death is determined.
	The Texas protocol calls for each medical professional on the drug team to have at least one year of medical experience. TDCJ Protocol § IV.A. AR at 89.	The 2019 Protocol does not clearly guarantee that any medically trained personnel will participate in executions. Nor does it require that medically-trained personnel have one year of medical experience, allowing instead for them to have "necessary training and experience," without any indication of what that is. 2019 Addendum ¶ D; AR at 1069.
	The Texas protocol provides that "[e]xpiration dates of all applicable items are to be checked on each individual item. Outdated items shall be replaced immediately." TDCJ Protocol § V.B.4; AR at 90. This requirement applies to both "chemicals used in lethal injection executions" as well as "the equipment and supplies necessary to perform the lethal injection." TDCJ Protocol § V.B.1-2; AR at 89.	The 2019 Protocol has no similar requirement.
Virginia	Virginia law provides condemned prisoners with a choice between electrocution and lethal injection. VA Code Ann. § 53.1-234.	The BOP's 2019 Protocol mandates that executions be carried out by lethal injection. 2019 Addendum ¶ A; AR at 1069.
	The current lethal injection protocol in Virginia calls for serial administration of 3 drugs: (1) midazolam (sodium thiopental or pentobarbital may be substituted); (2) rocuronium bromide (pancuronium bromide may be substituted); and (3) potassium chloride. VADOC Operating Procedure 3.	The 2019 Protocol mandates that executions be carried out by Pentobarbital Sodium. 2019 Addendum ¶ C; AR at 1069.

	The Virginia protocol requires that a physician employed by the Virginia Department of Corrections (or the physician's assistant) be present during the execution. VADOC Operating Procedure 1. The physician observes the heart monitor during the execution process. *Id.* at 11. Virginia law also requires a physician to pronounce death. *Id.*	The 2019 Protocol does not require the presence of a physician.
	The Virginia protocol requires all execution team members, including medical personnel, to participate in trainings. The IV Team receives training from a physician at least quarterly. VADOC Operating Procedure 17.	The 2019 Protocol does not require that medically licensed/certified personnel participate in training.
	Virginia codifies the use of compounded drugs, authorizing the Director of the Department of Corrections to enter into contracts with pharmacies or outsourcing facilities for the compounding of drugs necessary to carry out an execution by lethal injection. Virginia Code § 53.1-234.	The 2019 Protocol does not address the use of compounded drugs.
	Virginia's protocol requires that the execution team verify the labels and expiration dates of the drugs before the drugs are loaded into syringes for use. VADOC Operating Procedure 9.	The 2019 Protocol does not require that expiration dates be checked.
	Virginia's protocol provides that upon medical authorization the prisoner shall "be offered ten milligrams of valium" prior to the execution. VADOC Operating Procedure 9.	The 2019 Protocol does not provide for pretreatment.